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T-D

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/294,964 04/20/99 BILSTAD

A 1417B-P-316

IM62/1206

EXAMINER

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ART UNIT

PAPER NUMBER

1744

DATE MAILED:

12/06/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)
	09/294,964	BILSTAD ET AL.
	Examiner Imad Soubra	Art Unit 1744

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

1) Responsive to communication(s) filed on 21 September 2000.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-56 is/are pending in the application.

4a) Of the above claim(s) 18-33 is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-17 and 34-56 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claims 18-33 are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on 20 April 1999 is/are objected to by the Examiner.

11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) All b) Some * c) None of the CERTIFIED copies of the priority documents have been:

1. received.

2. received in Application No. (Series Code / Serial Number) _____.

3. received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

15) Notice of References Cited (PTO-892)

16) Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2 and 5.

18) Interview Summary (PTO-413) Paper No(s). _____

19) Notice of Informal Patent Application (PTO-152)

20) Other: _____

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-17 and 34-56, drawn to sterilization using gas contact means, classified in class 422, subclass 22.
 - II. Claims 18-33, drawn to sterilization using fluid contact means, classified in class 422, subclass 49.

The inventions are distinct, each from the other because: group 1 teaches that the gas is acted on the ends of the tube; on the other hand, group 2 teaches that a fluid is applied at the end of the tube.

During a telephone conversation with Robert W. Diehl on 11/21/00 a provisional election was made without traverse to prosecute the invention of Method and Apparatus for Manipulating Pre-Sterilized Components in an Active Sterile Field, claims 1-17 and 34-56. Affirmation of this election must be made by applicant in replying to this Office action. Claims 18-33 withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Drawings

2. The drawings filed on 4/20/99 are objected to by the Draftsperson under 37 CFR 1.84 or 1.152 for the reasons indicated in the Notice of Draftsperson's Patent Drawing Review. The Examiner will require submission of new, corrected drawings when necessary. Corrected drawing must be submitted according to the instructions on the back of the Notice Review form.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 54 and 55 recites the limitation "mechanical actuator". There is insufficient antecedent basis for this limitation in the claim. Please clarify what and how a "mechanical actuator" operate and function in the claimed invention. If this statement is answered in all instances, the rejection will be overridden.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1-3, 14-17, 34-36 and 46-47 are rejected under 35 U.S.C. 102 (b) as being anticipated by Granzow et al. Granzow et al inherently discloses the same method and system for sterilizing and adjoining two ends of a tube exposing the ends to radiant energy for a certain period of time. Granzow et al teaches to utilize radio frequency energy of the like as the radiant energy, opaque wall portions 30 (column 4, lines 15-23). The reference also teaches that a sterile connection can be made by briefly exposing the infrared radiation, to melt the opaque wall sections, fusing them together and forming an aperture through the sections (column 4, lines 24-41). Granzow further teaches that a laser may also be used as desired to provide the radiant energy (column 2, lines 31-41). In addition, the reference refers to the drawing which is an elevated view of a pair of conduit ends, the other ends of which may be connected to a pair of blood bags or the like, each terminating in a pair of housings which carry an opaque, thermoplastic wall portion in accordance with his invention (column 2, lines 48-53).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 4-7, 37-40 and 48-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Granzlow et al in view of Wakalopulous. Granzlow et al. fails to disclose the voltage ranges used to conduct the method. However, Wakalopulous teaches the voltage ranges used to curing hot melt adhesives. The ranges stated in the claimed invention reads on what the patent of Wakalopulous uses. For instances, the reference teaches that the first high voltage, 30 kV, being a lower voltage, will affect primarily the surface of the material being treated. The second high voltage, 60 kV, being a higher voltage, will affect the surface, but with a greater amount of penetrating power, will also affect a greater depth of material (column 6, lines 24-58). Therefore, it would have been obvious to one having ordinary skill in the art at the time that the invention was made to determine the voltage ranges and incorporated those ranges into the patent of Granzow et al and disclosing those voltage ranges which is notoriously well known in the art.

6. Claims 8-13, 41-45 and 50-56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Granzlow et al in view of Caputo et al. Granzlow et al fails to disclose the gas treatment, UV and ozone exposure and the system being automated. However, Caputo et al teaches all these elements in his inventions. The reference teaches that the operation is being controlled by the central processing unit (CPU) (column 9, lines 4-20). Caputo et al further teaches that the treatment of hydrogen peroxide and peracid gas to sterilize objects is notoriously well known in the art (column 7, lines 21-45). The reference also

teaches that UV (column 8, line16) and ozone (column 1, line 60) formed from current whereby articles are sterilized. Therefore, it would have been obvious to one having ordinary skill in the art at the time that the invention was made to incorporate these missing elements into the invention of Granzlow and Wakalopulos and claim these limitations into the claimed invention as described in the application.

Conclusion

7. Any inquiry concerning this communication from the examiner should be directed to Imad Soubra whose telephone number is (703) 305-3605. The examiner can normally be reached on 8:30 am to 4:30 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Warden can be reached on (703) 308-2920. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3599 for regular communications and (703) 305-5408 for After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1193.

Imad Soubra
November 29, 2000

Robert J. Warden, Sr.
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